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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,881	04/18/2000	WILLIAM IAN DAVID	9267.8	6916

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EXAMINER

MARSCHER, ARDIN H

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,881

Applicant(s)

DAVID ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed 2/23/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NON-STATUTORY SUBJECT MATTER

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is reiterated and maintained from the previous office action, mailed 9/22/03. Applicants argue that the present process starts with measurements of physical objects. In response, such a measurement limitation is not seen in the claims. Claim 1, for example, cites a first step of "providing a powder diffraction pattern...". Providing is not specifically a measurement practice. Providing is a data manipulation limitation wherein data has been provided regarding a powder diffraction pattern and thus is a non-persuasive argument. Applicants also argue that the claimed process falls within the safe harbor of the "Manipulation of Data Representing Physical Objects" as in MPEP § 2106.IV.B.2.(b).i. Consideration of this section of the MPEP reveals that therein is a section entitled "Manipulation of Data Representing Physical Objects or Activities (Pre-Computer Process activity)". Consideration of said section reveals that it

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states that another statutory process is "one that requires the measurements of physical objects...". As noted above, the instantly claimed providing step does not require any measurement per se. The MPEP explains further that "(data-gathering step did not measure physical phenomenon)". This section goes on to summarize several measurement practices or transformation of signals from physical objects into computer data. Applicants may overcome this rejection by claim amending that specifically supports such transformation of signals.

LACK OF SCOPE OF ENABLEMENT

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the fitness calculation set forth in claim 5, does not reasonably provide enablement for any generic fitness calculation as cited without limitation in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those

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in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

This rejection is reiterated and maintained from the previous office action, mailed 9/22/03. Applicants argue that genetic engineering is believed to be erroneous. In response applicants' own first paragraph of the specification directs the invention to "large organic molecules, such as pharmaceutical compounds" which clearly is directed to the realm of genetic engineering wherein pharmaceutical compounds are routinely practiced. Applicants then argue generally that genetic algorithms are well known in general. In response the basis of the rejection is undue experimentation regarding the calculation of fitness and not a generic genetic algorithm as summarized above in the basic statement of the rejection. Thus, applicants' arguments are not directed to the basis of the rejection and therefore non-persuasive. Applicants then point to the specification at citations on pages 4, 8, and 9. Consideration of said citations reveals that these citations lack any guidance for enablement of fitness calculation. In fact, these citations fail to include even the word "fitness" anywhere therein. Applicants also have not argued or pointed to what may be a functional equivalent to fitness in these citations or elsewhere. Thus, the enablement of fitness calculation still is deemed to be limited to the claim 5 practice as stated above as instantly disclosed.

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VAGUENESS AND INDEFINITENESS

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is reiterated and maintained from the previous office action, mailed 9/22/03. Applicants argue that Miller indices are part of the normal vocabulary of persons skilled in the crystallography arts, as evidenced by secondary material previously submitted. In response, the instant claims do not cite Miller indices per se anywhere. Additionally a review of previously submitted documents on this issue has failed to reveal an art recognized Miller indices definition as suggested by applicants. Applicants are requested to point out such art recognized indices as to also their correspondence to claim 5 parameters.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).
The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

May 28, 2004

Ardin H. Marschel 5/28/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER